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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,297	10/28/2003	Roy Chung	MCROD-002CB	4182

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,297	CHUNG ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 09/813,071; 09/295,487 and 09/195,309 fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. None of the previously filed application provides adequate support for a dye particle comprising at least two ligands analog proteins absorbed thereon, where each of the analog protein binds with receptors for dissimilar first and second ligands.

Therefore, the instant invention is only entitled to a filling date of 28 October 2003.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Van Hoegaerden (US 5,405,784).

Van Hoegaerden discloses fluorescent latex beads having more than one antiligands fixed to their surface. The antiligands are specific to more than one substances or ligands to be sought. See column 3, lines 27-68 and column 4, lines 16-22. See also column 11, example 8 and claims 8 and 11. Even though Van Hoegaerden does not specifically state that the antiligands are "ligand analog protein", these designations

are seen to be the same since the antiligand of Van Hoegaerden is defined as molecular structure capable of recognizing and binding specifically to the organic, biological or medicinal substances to be detected. Van Hoegaerden also teaches that the beads are suitable for direct, indirect sandwich or competitive assays.

4. Claim 1 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Nelson et al (US 6,974,704).

Nelson discloses affinity reagents comprising one or several different antigens immobilized to a solid substrate. See column 5, lines 27-63. The solid substrate is selected from agarose beads, nylon, metals, glass, silicon and organic membranes. See also claims 6 and 11.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Hoegaerden or Nelson, each in view of Chudzik et al (US 5,981,298) and The Triage Panel for Drugs of Abuse, Biosite Diagnostics, 1991.

See the discussion of Van Hoegaerden and Nelson above. These references differ from the instant invention in failing to teach conjugating morphine-3-beta-D-glucuronide or amphetamines to the dye particles.

Chudzik, however, discloses reagents and method for detecting the presence of one to four drugs in a single sample of urine or serum such as cocaine, amphetamines, their derivatives and metabolites (column 3, lines 66 through column 4, line 5; and column 4, lines 64 through column 5, lines 5). Chudzik teaches conjugating gold sol particles or dyes with drug conjugates (column 6, lines 51-65), such as morphine, morphine glucuronide, amphetamines, etc. (column 9, lines 21-35).

The Triage Panel teaches that is desirable detect drugs of abuse because they continues to be an increasingly significant social and economic problem. Opiates, cocaine, THC, amphetamines as well as other tranquilizers, anti-depressants, barbiturates and opiate compounds can all be detected using visually read immunoassays. The triage Panel discloses monoclonal antibodies against the major metabolites of phencyclidine, amphetamines, opiates, barbiturates etc. for use in immunoassay and further discloses an extensive list of drugs that may be tested including morphine-3-β-glucuronide.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the affinity reagents taught by Van Hoegaerden or Nelson to include ligand analog such as morphine glucuronide and amphetamine since Chudzik and The Triage Panel teach that such conjugates are well known in the

art. A skilled artisan would have had a reasonable expectation of success in replacing the antiligand taught by Van Hoegaerden or Nelson with the ligand analog of morphine or amphetamine as taught by Chudzik and The Triage Panel because such a change is a mere alternative and functionally equivalent conjugation technique.

Even though these references do not specifically teach that the particulate dye is conjugated with 3, 4 or 5 different ligand analogs, such a reagent is obvious in view of the teachings of Van Hoegaerden, Nelson, Chudzik and The Triage Panel. Each of these references recognize the needs for detecting more than one analytes in the same sample and provide reagents and means for doing so.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 8/22/06